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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Further to our letter of October 27, 2010, the USPTO has determined that U.S. Patent No. 6,034,267 claims the new drug product, METVIXIA® (methylaminolevulinate hydrochloride) which, according to FDA's letter of March 7, 2007, was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. As per our letter of October 27, 2010, the subject patent was determined to be eligible for patent term extension in *Photocure v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Kenyon & Kenyon
One Broadway
New York, NY 10004

RE: METVIXIA® (methylaminolevulinate hydrochloride)
Docket No. FDA-2007-E-0104